

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)



(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PWO-P001-043	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/IB2004/003676	International filing date (day/month/year) 10.11.2004	Priority date (day/month/year) 10.11.2003	
International Patent Classification (IPC) or national classification and IPC A61F2/46			
Applicant PRECIMED, S.A. et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> <i>(sent to the applicant and to the International Bureau) a total of 4 sheets, as follows:</i></p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</i></p>			
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application 			
Date of submission of the demand 04.08.2005	Date of completion of this report 14.02.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Storer, J Telephone No. +49 89 2399-7247		



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2004/003676

Box No. I Basis of the report

- With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
- With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-9 as originally filed

Claims, Numbers

1-21 received on 08.08.2005 with letter of 04.08.2005

Drawings, Sheets

1/20-20/20 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:

- the description, pages
- the claims, Nos.
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to sequence listing (*specify*):

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages
- the claims, Nos.
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2004/003676

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-21
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-21
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-21
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/IB2004/003676

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1 : WO 01/06964 A (TILLANDER, BO; PALM, LARS; IVARSSON, INGEMAR) 1
February 2001 (2001-02-01)

Document D1 is regarded as being the closest prior art to the subject-matter of claim 1, the document disclosing (the references in parentheses applying to this document):
an acetabular cup impactor for aiding a surgeon in controlling the installation of a hip prosthesis, the inserter comprising:
an impactor head (14, 15, 16);
a housing (2) attached to the head, the housing enclosing a drive train (1) having, at a far end, a thread suitable for engaging a prosthesis, and at the opposite end a handle (5) which facilitates turning of the drive train by the operator; and
a locking mechanism (3) associated with the housing which selectively locks the drive train, and thus the prosthesis, in position,
wherein the opposite end of the drive train has a latch device (3) which enables quick removal of the drive train from the housing for cleaning and sterilisation (see page 5, lines 6-20 and figure 1).

The subject-matter of claim 1 differs from this known device in that the housing has at least one bend permitting the housing to avoid anatomical structures or tissue during use in surgery. The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as being how to provide an acetabular impactor better suited to passing through a miniature incision without impinging on the skin.

The solution to this problem proposed in claim 1 is considered to involve an inventive step since no document of the available prior art shows or suggests the provision of a housing with at least one bend to solve the given technical problem.

The industrial applicability of the invention is self-evident, therefore claim 1 satisfies the

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.
PCT/IB2004/003676

requirements of Article 33(2)-(4) PCT.

Since claims 2-21 are dependent on claim 1, these also meet the requirements of the PCT with respect to novelty and inventive step.

It is noted that claim 1 has not been delimited with respect to the closest prior art (document D1), as required by Rule 6.3(b) PCT, and that document D1 has not been identified in the description, as required by Rule 5.1(a)(ii) PCT.

IS/64) 3676

PWO-P001-043

What is claimed is:

1. An acetabular impactor (10, 10', 10'') for aiding a surgeon in controlling the installation of a hip prosthesis (11), the impactor comprising:

(a) an impactor head (20);

(b) a housing (12, 12', 12'') attached to the impactor head, the housing having at least one bend permitting the housing to avoid anatomical structures or tissue during use in surgery and enclosing a drive train (14, 14', 14'') having, at a far end (134), a prosthesis engaging thread (124), and at the opposite end (42'), a handle (20, 20', 20'') which facilitates turning of the drive train by the operator; and

(c) a locking mechanism (44, 50, 52, 54, 56, 60, 62, 67, 68; 124, 130, 142, 146; 180, 193, 194, 195, 196, 200, 202, 206, 210, 212, 14) associated with the housing which selectively locks the drive train, and thus the prosthesis, in position.

wherein further the opposite end (42') of the drive train has a latch device (52, 54, 56, 60, 62; 44, 50; 180) which enables quick removal from the housing for cleaning and sterilization.

4. The acetabular impactor (10, 10', 10''), wherein the drive train (14, 14', 14'') includes at least one u-joint (30') located so as to transmit torque through a bend in the housing (12, 12', 12'').

5. The acetabular impactor (10, 10', 10'') of claim 1, wherein the housing (12, 12', 12'') is C-shaped.

4. The acetabular impactor (10) of claim 1, wherein the locking mechanism (44, 50, 52, 54, 56, 60, 62, 67, 68) comprises a drive train (14) having a threaded, prosthesis engaging tip (146a), the drive train further including a lever link (42) which is disposed in the housing (12) so as to rotate on a fulcrum (32), such that, actuation of the lever link draws the threaded tip (146a) into the housing and, when connected to a prosthesis (11), draws the prosthesis against an impaction surface (140a), wherein sufficient friction may be generated therebetween to lock the prosthesis in place.

5. The acetabular impactor (10) of claim 4, wherein the link lever (42) has a knob (20) attached to its extreme end, the knob enabling a user to orient the tip (146a).

REPLACEMENT SHEET

IS/04/3676

PWO-P001-043

6. The acetabular impactor (10) of any one of claims 1-5, wherein a lockable, variable length link (56) is attached between the link lever (42) and the housing (12) in order to permit a user to vary pressure that the tip can exert against the impaction head (140).
7. The acetabular impactor (10) of claim 6, wherein the variable link (56) is infinitely variable and unlockable via a latch (68) in order to permit release of pressure on the prosthesis (11).
8. The acetabular impactor (10) of claim 7, wherein the prosthesis engaging tip (146a) is connected by way of a first U-joint (30') to a lever (32) which slides in a pivoting sleeve (34) fixed to the housing via a first pivot (36).
9. The acetabular impactor (10) of claim 1, wherein a one-way catch mechanism (67) prevents a rod (56) connected to the second lever (42) from sliding out of the housing (12) unless an unlock lever (68) is activated.
10. The acetabular impactor (10, 10', 10'') of claim 1, wherein the impactor head (20) is covered by an impactor head covering (140), made of a shock-absorbing material, in order to absorb the impact stresses incurred during use of the impactor.
11. An acetabular impactor (10') of claim 1, wherein the locking mechanism (124, 130, 142, 146) is an expandable collet (120) which a knob (20'), adjacent the handle (60), expands when turned in one direction so as to lock the collet (120) against a surface of a prosthesis (11) in order to prevent the prosthesis from rotation, thus enabling the surgeon to pre-set and lock the position of the prosthesis prior to the installation thereof.
12. The impactor (10') of claim 11, wherein the collet (120) is comprised of two jaws (124) having opposite ends (125, 126) pivoting on a fulcrum (32), one end of which being adapted to engage an interior surface of a prosthesis (11), the prosthesis engaging ends being drawn away from one another when a actuator piston (146), which passes through the fulcrum (130), is draw therebetween, thereby eliminating the need of threading the acetabular prosthesis (11) onto the tip (125) of the impactor as the prosthesis can simply be placed over the collet and the collet expanded so as to grip the internal threads (122) of the prosthesis.

REPLACEMENT SHEET

18/04/3676

PWO-P001-043

13. The impactor (10') of claim 12, wherein the fulcrum (32) is mounted in a cage (142) through which the actuator piston (146) passes, the actuator piston having a shoulder (143) bearing against a surface (142') of the cage opposite the prosthesis engaging ends (125) of the jaws (124), such that, as the actuator piston is being activated to separate the prosthesis engaging ends of the jaws, a shoulder (146e) of the piston contacting the surface compresses the jaws into the cage, thereby drawing the jaws into the impactor and, when connected to a prosthesis, thereby drawing the prosthesis against an impaction surface (140a) so as to firmly fix the prosthesis against the impaction surface.

14. The impactor (10') of claim 13, wherein the collet (120) is provided with external, three-dimensional structures (124) which engage with corresponding structures (122) on the prosthesis (11).

15. The impactor (10') of claim 14, wherein the three dimensional structures are threads (122).

16. The impactor (10') of claim 14, wherein the three-dimensional structures are grooves.

17. The impactor (10') of claim 14, wherein the three-dimensional structures are divots.

18. The acetabular impactor (10') of claim 11, wherein the drive train (14') includes at least one u-joint (30') located so as to transmit torque through -at a bend in the housing (12').

19. The acetabular impactor (10') of claim 11, wherein the housing (12') is C-shaped.

20. The acetabular impactor (10'') of claim 1, wherein further, the locking mechanism (180, 193, 194, 195, 196, 200, 202, 206, 210, 212) is made up of a latch housing (180) which is constrainable against rotation while being urged part-way into a recess (184) toward the engagement end (186) of an impactor head (140) by a spring (190) captured between the latch housing (180) and a shaft (212) of the drive train, the spring urging the latch housing against a cam stop (194) when a trigger (196, 200) is positioned so as to selectively:

REPLACEMENT SHEET

IB/04/3676

PWO-P001-043

i) enable the drive train to be turnable within the housing (12'') by the operator rotating the handle (160), the cam stop (194) being connected to a shaft (200) to which an actuator component (196) is attached,

ii) enable a user to turn the cam stop (194) in a position to block further movement of the latch housing (180) into the recess (184), such that when the cam stop is turned so that it does not block further entry of the latch housing into the recess(184), catches (206) inside the latch housing are urged into engagement with serrations (210) cut into the outer circumference of a component (212) of the drive train, wherein the engagement of the catches (206) into the serrations (210) constrains the latch housing (190) against rotational movement and locks the drive train (14'') against rotational movement,

the selectivity enabling the surgeon to pre-set and lock the position of the prosthesis (11) prior to the installation thereof, wherein the latch housing (180) may be unlatched from the housing so as to enable quick and invention is easily cleanable.

21. The acetabular impactor (10'') of claim 1, wherein the housing (12'') is C-shaped, in order to minimize the invasiveness of the surgery by better clearing anatomical structures and tissue.

REPLACEMENT SHEET

13

AMENDED SHEET

08/08/2005